REMARKS

With entry of this amendment, claims 1-29 and 40-45 are pending in this application. Claims 1-29 are subject to a requirement for election of species, as set forth in the Restriction Requirement mailed October 9, 2003. Claims 30-39 stand withdrawn from further consideration as allegedly drawn to a patentably distinct invention. Applicant cancels claims 30-39 to expedite more compact prosecution of this case. Applicant reserves the right to file a divisional or related application to prosecute the subject matter of these claims.

Claim 1 is amended to further clarify the claim language. In particular, the claim is amended to recite a method for decreasing the effective amount of a therapeutic agent administered to a subject having an autoimmune condition, comprising co-administering to the subject an effective amount of a sleep restorative agent or a pharmacologically acceptable addition salt thereof, and a therapeutic agent; whereby the effective amount of the therapeutic agent is decreased, as compared to a subject not receiving the sleep restorative agent increased. Support for this amendment is found throughout the instant application, such as, for example, at page 5, lines 13-24.

Applicant adds new claims 40-45. Support for these claims is found throughout the instant specification, such as, for example, at the following pages: page 2, line 29 to page 3, line 23; page 4, lines 12-23; page 5, line 13 to page 6, line 14; page 8, line 8 to page 9, line 11; page 11, lines 1-18; page 12, line 19 to page 13, line 31; and page 19, line 17 to page 28, line 19. No new matter is believed to be added by these amendments.

Applicant believes no additional claim fees are due because Applicant canceled ten claims and added six claims.

This second restriction requirement requires Applicant to elect a single disclosed species relating to a method and a single combination of a sleep restorative agent and a therapeutic agent for prosecution on the merits. The Office states that the claims shall be restricted to the elected species if no generic claim is finally held to be allowable.

The Office alleges that previously elected Group I (claims 1-29) encompasses numerous patentably distinct species, designated Groups I-XXXVII in the communication. The Office requires Applicant to elect one group within Groups I-XXXVII. The Office further requires

Applicant to elect a single sleep restorative agent (referring to pages 7 and 8, paragraphs "1" and "2" of the Restriction Requirement) and a single therapeutic agent (referring to page 8, paragraph "3," "I-ix and xv") for examination purposes. The Examiner alleges that pending claims 1, 8, 10 and 22 are generic.

The Office further requires Applicant to provide a listing of all claims readable on the elected species. The Office acknowledges that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species included within the allowed generic claim. Although the instant species are designated as "groups," Applicants understands the groups set forth in this Restriction Requirement are "species" within the Group set forth in the Restriction Requirement mailed June 30, 2003.

Initially, Applicant notes that the listing of "method" species set forth in the Restriction Requirement contains a number of minor typographical errors, which might cause confusion during prosecution of this application or related a application. In particular, the numbering of the "method" species I-XXXVII is not consecutive (*e.g.*, there is no group XVI and there are two Groups XXVI, Groups XXXII and Groups XXXIV).

Applicant respectfully request the Examiner reconsider the present restriction requirement. The presently claimed invention relates to methods which together comprise a single inventive concept. Under 35 U.S.C. § 121, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) the inventions must be independent or distinct as claimed; and

(2) there must be a serious burden on the examiner if restriction is not required.

See MPEP § 803.

The MPEP states that where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. *See* MPEP §803. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. In order to show undue burden resulting from searching difficulties, the Examiner must show that the restricted groups have separate classification, acquired a separate status in the art, or that

searching would require different fields of search. According to the MPEP, where the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions. See, MPEP § 808.02 (C).

Further, under current PTO examination practice, claims 37 C.F.R § 1.141 provides that a reasonable number of species may be claimed in an application. Thus, Applicants respectfully submit that the presently set forth Groups, or at least a reasonable number of Groups, can readily be searched together without an undue burden, particularly since the groups are generally drawn to methods of administering one or more therapeutic agents and one or more sleep restorative agents to increase the efficacy, or to spare the requirement for, the therapeutic agent(s).

If the Examiner believes a telephone interview would be useful to resolve any issues in this case, the Examiner is welcome to contact the undersigned representative of the Applicant.

Respectfully submitted,

Dated: 1/9/04

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